

K112200

510(k) Summary

[Refer to 21 CFR 807.92]

SEP 6 2012

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Date Prepared: August 24, 2012

Proprietary Name: Focus Touch™ Conception System

Common Name: Conception Assistance Kit

Classification Name: Kit, Conception-Assist, Home Use (Product Code: OBB)

Classification Panel: Obstetrical/Gynecological

Regulation: 21 CFR § 884.5250, Cervical Cap

Predicate Devices:	Manufacturer Conceivex, Inc	Device Name Conception Kit	510(k) Number K063227
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Reason for Submission New Device

510(k) Number: K112200

Description of Device

The Focus Touch™ Conception System includes detailed Instructions for Use, one *Conceptacle* and one plastic applicator. The system can be purchased packaged in a quantity of one (1) or three (3) individually packaged systems.

Once the couple has decided to attempt to become pregnant, the Focus Touch™ Conception System Instruction for Use recommends using the device during female's most fertile days in a given month. During sexual intercourse, semen will be collected using the *Conceptacle*, a cervical cap that is pre-inserted into a condom-like sheath. The male removes the *Conceptacle*

from the penis by rolling it down and separating it from the penis. After removal, the rim of the cervical cap is lightly pinched so that the Condom-like Sheath can be separated. (The Cervical Cap and Condom-like Sheath are separated in two separate parts). The semen is contained in the cervical cap and its reservoir. The second component, the Applicator, is used for ease of transition of the Cervical Cap to the cervix. The applicator seals the Cervical Cap and contains the semen for transition through the vaginal tract, assisting the female in guiding the cap to the cervix and releasing the semen and the cap in front of the cervix. When the cervical cap is loaded onto the applicator (while it is still outside of the body), the Retainer locks onto the Cervical Cap and is delivered with the Cervical Cap intravaginally. The Retainer also has a removal cord that is attached for withdrawal. The Cervical Cap and Retainer then remain in place for up to 6 hours.

Indication For Use

The Focus Touch Conception System is indicated for assisted insemination in instances where low sperm count, sperm immobility, or hostile vaginal environment has been diagnosed. The system (cervical cap in a condom-like silicone sheath) is used to collect semen into a cervical cap, and then deliver the cap to the outside of the cervix as an aid to conception. It is to be used at home following physician instruction. The Focus Touch Conception System should not be left in place for longer than 6 hours.

Comparison between predicate and proposed device

The tables below compare the two devices:

Device Similarities:

Device	Predicate - Conceive Inc. Conception Kit	Proposed - Focus Touch Conception System	Conclusion
Indication for Use	The Conceive Conception Kit is indicated for assisted insemination in situations in which low sperm count, sperm immobility, or hostile vaginal environment have been diagnosed. The kit is used for semen collection and placement into the bowl of a cervical cap as an aid to conception. It is to be used at home following physician instruction. The Cap should not be left in place for longer than 6 hours.	The Focus Touch Conception System is indicated for assisted insemination in instances where low sperm count, sperm immobility, or hostile vaginal environment has been diagnosed. The system (cervical cap in a condom-like silicone sheath) is used to collect semen into a cervical cap, and then deliver the cap to the outside of the cervix as an aid to conception. It is to be used at home following physician instruction. The Focus Touch Conception System should not be left in place for longer than 6 hours.	Same
Usage	Prescription Use. For use at	Prescription Use. For use at	Same

	home following physician instruction.	home following physician instruction.	
User Group	Couples who are trying to conceive and have been diagnosed with low sperm count, sperm immobility, or hostile vaginal environment.	Couples who are trying to conceive and have been diagnosed with low sperm count, sperm immobility, or hostile vaginal environment.	Same
Material Composition of Cervical Cap	Silicone Cervical Cap	Silicone Cervical Cap	Same
Insemination Technology	Cervical Cap Insemination	Cervical Cap Insemination	Same
Biocompatibility	Materials tested and shown to be biocompatible.	Materials tested and shown to be biocompatible.	Same
Sperm Compatibility	Human Sperm Survival Assay Tested to demonstrate that device materials have no deleterious effects on human sperm.	<i>Conceptacle</i> Human Sperm Survival Assay (HSSA) Tested. To pass the HSSA test, the human sperm must demonstrate forward progressive motility rate of $\geq 80\%$ of the initial forward progressive motility sperm swim up after 6 hours of sample preparation.	Same
Sterility	Nonsterile	Nonsterile	Same
Single use	Yes	Yes	Same

Device Differences:

Device	Predicate - <i>Conceivex</i> Inc. Conception Kit	Proposed - Focus Touch Conception System
Semen Collection Method	A collection condom is used during intercourse to collect semen.	The Focus Touch™ Conception System does not contain a separate collection condom, rather the collection cervical cap and condom-like sheath are pre-assembled into one unit.
	<p>Discussion:</p> <p>Collection is still performed in the same manner as it is with the predicate device. Usability and acceptability testing was successfully performed to validate that the use of the <i>Conceptacle</i> for semen collection was comfortable (slip, breakage, ability to ejaculate) and adequate (able to collect and contain semen). Therefore, the semen collection method utilizing the <i>Conceptacle</i> (cervical cap and condom-like sheath assembly) is substantially equivalent to and the collection method of the predicate device.</p>	
Collection Condom Material	Polyurethane	The condom-like sheath component of the <i>Conceptacle</i> is made from silicone.
	<p>Discussion:</p> <p>Silicone has been used historically for medical devices used in the vaginal tract.</p>	

	<p>The Condom-like Sheath of the <i>Conceptacle</i> is very similar in malleability to standard polyurethane condoms with a durometer of 30-40 on the Shore A scale. The device has been shown to be biocompatible and acceptable as a semen collection device with regard to comfort (slip, breakage, ability to ejaculate) and adequacy (ability to collect and contain semen) in validation testing. Therefore, the material used for the condom-like sheath of the proposed device is substantially equivalent to the material used for the condom for the predicate device.</p>	
Placement and Delivery Method	<p>The device is placed into the vagina and in front of the cervical os by hand.</p>	<p>The Focus Touch™ Conception System uses an applicator for placement and delivery of the cervical cap to the cervical os.</p>
	<p>Discussion: The applicator component, for which biocompatibility and usability have been demonstrated during testing, allows the user to insert the cervical cap into the vaginal tract without the use of the user's hand. It is performed in a similar manner as inserting a tampon with a plastic applicator. It has smoothness requirements for comfort and safety and allows for insertion and placement. Therefore, the placement and delivery method of the proposed device is substantially equivalent to that of the predicate device.</p>	
Removal Method	<p>The proposed device contains a loop that is molded with the cervical cap. The user reaches into the vagina and grasps the loop to remove the device.</p>	<p>The Focus Touch™ Conception System applicator features a mechanism which applies a removal cord to the cervical cap (during the process of loading the applicator) to aid in removal of the device.</p>
	<p>Discussion: The removal means of the looped removal device to grip and pull to withdraw is the same for the predicate and proposed device. The difference is that the remove cord on the proposed device remains outside of the vagina and provides for removal of the device without insertion of the hands into the vaginal opening, as was demonstrated during Usability testing. Testing was also performed to verify that the pull strength of the collet/string attached to the cervical cap is sufficient to ensure that the cap will not be separated from the collet. Therefore the removal cord method of the proposed device is substantially equivalent to that of the predicate device.</p>	

Testing Summary

Biocompatibility Testing performed on the device demonstrated that like the predicate device, the Focus Touch Conception System is considered non-cytotoxic, is not an irritant and did not elicit a sensitization response. Human Sperm Survival Assay (HSSA) testing was performed on the silicone *Conceptacle* (Cervical cap inserted into condom-like sheath) to demonstrate that like the predicate device, the Focus Touch collection device and cervical cap, *Conceptacle*, material has no deleterious effects on human semen. Bench testing was performed to verify that the condom-like sheath of the Focus Touch *Conceptacle* exceeded the minimum requirements for

burst pressure and volume for commercially available condoms. Bench testing demonstrated that the pull strength of the withdrawal cord, specifically Cervical Cap/Collet Separation Force for the Focus Touch System, was met for all systems tested. A shelf life study was performed to verify that all components of the Focus Touch System were shown to function properly and according to their design intent following a minimum real-time storage during of and/or accelerated aging period equivalent to six (6) months. Clinical human factors/usability testing was performed to validate the usability of the device. Specifically, Study 1 testing was performed with the cervical cap and applicator to demonstrate that the end user can understand the Instructions for Use, and manipulate, insert and remove the cap correctly without direct supervision. Study 2 testing was performed to demonstrate appropriate ease of use, comfort and acceptability and safety when used during sexual intercourse as a collection device. During Study 1, a physical examination occurred to verify safety of the device to the vaginal tract and all success criteria were met.

Conclusion

The differences between the predicate device and the Focus Touch™ Conception System have been evaluated through testing to show that they are not critical to the intended therapeutic effect of the device, nor do they affect the safety or effectiveness of the device when used as labeled. Therefore, the Focus Touch Conception System is substantially equivalent to the ConceiveX Conception Kit



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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SEP 6 2012

Re: K112200
Trade/Device Name: Focus Touch™ Conception System
Regulation Number: 21 CFR§ 884.5250
Regulation Name: Cervical cap
Regulatory Class: II
Product Code: OBB
Dated: April 18, 2012
Received: August 29, 2012

Dear Ms. Caporali Spaniel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

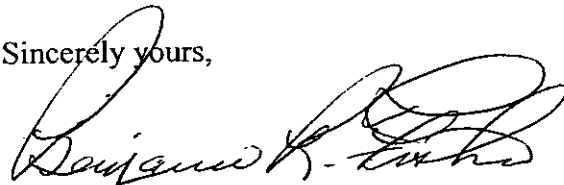
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher", is written over the typed name.

Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~PDB~~ K112200

Device Name: Device Name: Focus Touch™ Conception System

Indications for Use:

The Focus Touch Conception System is indicated for assisted insemination in instances where low sperm count, sperm immobility, or hostile vaginal environment has been diagnosed. The system (cervical cap in a condom-like silicone sheath) is used to collect semen into a cervical cap, and then deliver the cap to the outside of the cervix as an aid to conception. It is to be used at home following physician instruction. The Focus Touch Conception System should not be left in place for longer than 6 hours.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K112200